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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,428	04/18/2007	Johan Engstrom	HO-P02936US1	8156

29053 7590 03/15/2011
FULBRIGHT & JAWORSKI L.L.P
2200 ROSS AVENUE
SUITE 2800
DALLAS, TX 75201-2784

EXAMINER

SEIFU, LESSANEWORK T

ART UNIT	PAPER NUMBER
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1774

NOTIFICATION DATE	DELIVERY MODE
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03/15/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/587,428	Applicant(s) ENGSTROM ET AL.	
	Examiner Lessanework Seifu	Art Unit 1774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/07/11; 05/27/10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 26, 2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 10 recites the limitation "the R_{DS}" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 5-12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrison et al. (US 6,432,290).

Regarding claim 1, the reference Harrison et al. discloses a microfluidic device (20) comprising a microchannel structure in which there are two or more flow paths (21,38,23,25,27,28,28a,30,35) all of which comprises a porous bed I (30, 35) that is common for all of the flow paths (see Fig. 9) and is provided in a detection microcavity (see col. 12, lines 52-53 and col. 13, lines 52-57), which bed exposes an immobilized reactant R that is capable of interacting with a solute S that passes through the bed (see col. 17, lines 55 to col. 18, line 2), wherein at least one of the flow paths comprises a second porous bed II (25) that is placed upstream of porous bed I (30,35) and is dummy with respect to interaction with solute S but capable of interacting with a substance DS that is present in a liquid aliquot together with solute S and is capable of disturbing the result of the interaction between solute S and the immobilized reactant R (see col. 4, lines 12-19).

Regarding claim 2, the reference Harrison et al. discloses wherein porous bed I (30, 35) and porous bed II (25) are physically separated from each other (see Fig. 9).

Regarding claim 5, the reference Harrison et al. discloses that porous bed I (30, 35) and porous bed II (25) are made from packed bed of particles (see Fig. 3B and col. 2, lines 14-25).

Regarding claims 6 and 7, the reference Harrison et al. discloses that porous bed I (30, 35) and porous bed II (25) are solid phase material that are a size exclusion material (see col. 6, lines 7-15).

Regarding claim 8, the reference Harrison et al. discloses wherein at least one, two or more (28,28a,33,33a) of the remaining two or more flow paths is/are devoid of porous bed II (25) (see Fig. 9).

Regarding claim 9, the reference Harrison et al. discloses wherein the porous bed II (25) in the two or more flow paths comprises an immobilized reagent R_{DS} that is capable of interacting with the disturbing substance that is present together with a solute (see col. 17, lines 44-54).

Regarding claim 10, the reference Harrison et al. discloses that the immobilized reactant exposed in each porous bed (25, 30, 35) can be different (see col. 17, lines 39-67).

Regarding claim 11, the process steps recited in the claim read on the microfluidic device (20) and the exemplary microfluidic process disclosed in the reference Harrison et al. (see Fig. 9 and col. 17, lines 39-67).

Regarding claim 12, the reference Harrison et al. discloses a microfluidic device (20) comprising a microchannel structure that comprises two or more flow paths (21,38,23,25,27,28,28a,30,35) each of which comprises a porous bed I (30, 35) that is

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common for all of the flow paths and at least one of which (21,23) comprises a porous bed II (25) which is upstream of porous bed I (30, 35), wherein porous bed I (30, 35) is provided in a detection microcavity (see col. 12, lines 52-53 and col. 13, lines 52-57), and wherein one or both of porous bed I (30,35) and porous bed II (25) in the two or more flow paths comprises a solid phase material containing a generic ligand (see col. 12, lines 60-65).

Regarding claim 16, the reference Harrison et al. discloses an embodiment wherein there is only one flow path comprising both porous bed I (30,35) and porous bed II (25) (see Fig. 9).

7. Claims 1, 2, 5-9, 11, 12, 15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersson et al. (US 2003/0053934).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, the reference Andersson et al. discloses a microfluidic device comprising a microchannel structure (201) in which there are two or more flow paths (202, 203, 204, 205, 212, 219, 226, 227) all of which comprises a porous bed I (i.e. porous bed in element: 205) that is common for all of the flow paths (see parags. [0016] and [0017]) and is provided in a detection microcavity (see parag. [0111]), which bed

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exposes an immobilized reactant R that is capable of interacting with a solute S that passes through the bed (see parags. [0017] and [0081]), wherein at least one of the flow paths (204) comprises a second porous bed II (see parags. [0080], [0092] and [0093]) that is placed upstream of porous bed I and is dummy with respect to interaction with solute S but capable of interacting with a substance DS that is present in a liquid aliquot together with solute S and is capable of disturbing the result of the interaction between solute S and the immobilized reactant R.

Regarding claim 2, the reference Andersson et al. discloses wherein porous bed I (porous bed in element: 205) and porous bed II (i.e. porous bed in element: 204) are physically separated from each other (see Fig. 2a and parag. [0081]).

Regarding claim 5, the reference Andersson et al. discloses that the solid phase (i.e. porous bed) in elements 204 and 205 can in the form of a packed bed of particles (see parag. [0081]).

Regarding claims 6 and 7, the reference Andersson et al. discloses wherein at least one of porous bed I (i.e. porous bed in element: 205) and porous bed II (i.e. porous bed in element: 204) comprises a solid phase material that is a size exclusion material (see parag. [0080]).

Regarding claim 8, the reference Andersson et al. discloses wherein at least one, two or more of the remaining ones of the two or more flow paths (219,212) is/are devoid of porous bed II (see Fig. 2a).

Regarding claim 9, the reference Andersson et al. discloses wherein the porous bed II (i.e. porous bed in element: 204) in the two or more flow paths comprises an

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immobilized reagent R_{DS} that is capable of interacting with the disturbing substance that is present together with a solute (see parag. [0085]).

Regarding claim 11, the process steps recited in the claim read on the microfluidic device shown in Figure 2a and the exemplary microfluidic process recited in paragraphs [0110] and [0111] of the reference Andersson et al.

Regarding claim 12, the reference Andersson et al. discloses, a microfluidic device comprising a microchannel structure (201) that comprises two or more flow paths (202, 203, 204, 205, 212, 219, 226, 227) each of which comprises a porous bed I (i.e. porous bed in element: 205) that is common for all of the flow paths (see parags. [0016] and [0017]) and at least one of which (204) comprises a porous bed II (see parags. [0080], [0092] and [0093]) which is upstream of porous bed I, wherein porous bed I is provided in a detection microcavity (see parag. [0111]), and wherein one or both of porous bed I and porous bed II in the two or more flow paths comprises a solid material containing a generic ligand (see parags. [0017], [0087] and [0088]).

Regarding claim 15, the reference Andersson et al. discloses wherein the ligand is biotin or anti-biotins (see parag. [0088]).

Regarding claim 16, the reference Andersson et al. discloses an embodiment wherein there is only one flow path comprising both porous bed I and porous bed II (see Fig. 2a and parag. [0014]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (US 6,432,290).

Regarding claims 13-15, the claims depend on claim 12 such that the reasoning applied to claim 12 above in reference to Harrison et al. is applied herein for the dependent portion of the claims. The reference Harrison et al. is silent with respect to the specific kind of ligand immobilized on the beads which form the respective porous beds (25, 30, 35) in the reference Harrison et al. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have any suitable ligand immobilized on the beads which form each porous bed (25, 30, 35) in the reference Harrison et al., including in the configuration as claimed, because the reference Harrison et al. discloses that the microfluidic device of their disclosure allows for performing immunoassays using bead-based reagents (see col. 12 lines 35-50).

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lessanework Seifu whose telephone number is (571)270-3153. The examiner can normally be reached on Mon-Thr 9:00am-6:30pm; Fri 9:00am-1:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./
Examiner, Art Unit 1774

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1774